### REMARKS

Claims 1-49 were examined and reported in the Office Action. Claims 1-49 are rejected. Claims 1, 3, 8, 12, 20-23, 26, 33-34, 37 and 44-48 are amended. Claims 1-49 remain.

Applicant requests reconsideration of the application in view of the following remarks.

#### I. 35 U.S.C. § 103

A. It is asserted in the Office Action that Claims 1, 4-10, 13-24, 27-35, 38-49 are rejected in the Office Action under 35 U.S.C. § 103(a), as being unpatentable over U.S. Patent No. 6,272,370 issued to Gillies et al. ("Gillies"), in view of U.S. Patent No. 6,167,292 issued to Badano et al. ("Badano"). Applicant respectfully traverses the aforementioned rejection for the following reasons.

## According to MPEP §2142

[t]o establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (In re Vacck, 947 F.2d 488, 20 USPO2d 1438 (Fed. Cir. 1991)).

Further, according to MPEP §2143.03, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (<u>In re Royka</u>, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)," "All words in a claim must be considered in judging the patentability of that claim against the prior art." (<u>In re Wilson</u>, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), emphasis added.)

Gillies discloses a device and method for targeted drug delivery. The device disclosed in Gillies is "MR-visible." (See Gillies, Title; column 10, lines 56-61). The device includes a magnetic tip. In another embodiment, Gillies discloses an MR-visible microdialysis probe. (See Gillies, column 13, lines 37-42). Gillies further uses coils and an amplifier circuit for RF signals. Gillies, however, does not teach, disclose or suggest that geometric information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, and wherein the MRI system is unable to detect or will disregard MRI signals of the target markers within the anatomy as noise without using the stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system. Further, in Gillies, there is no mention of lowering of an MRI signal detection threshold.

Badano discloses a preprocedure step of taking a preprocedure image of an anatomic structure (i.e., a body part of a person) where the surgical operation is to be performed using marker elements for marking the anatomical structure. (Badano, column 6, lines 8-14). In other words, Badano teaches marking a body part with markers that are visible when taking an image. Badano does not teach, disclose or suggest insertion of a medical device into an anatomy where the medical device includes markers and geometric information on the markers is stored before insertion. The device of Badano is first fixed to a person (e.g., attached to a person's skull from outside the person's body). This anchor receives a support element that includes markers, which are never inserted into an anatomy as the markers are fixed to first and second support elements, which would cause death if inserted into a person's anatomy.

Moreover, the invention disclosed by Badano is completely different and incompatible from Gillies. That is, teachings from Gillies and Badano cannot be combined (i.e., Badano uses images made from the help of a device outside an anatomy while Gillies needs to view imaging with help from a device placed inside an anatomy).

Therefore, neither Gillies, Badano, and any resulting invention from the combination of the two teach, disclose or suggest Applicant's: amended claim 1 limitations of

a medical device adapted to be inserted into an anatomy; and a plurality of target markers disposed on a proximal portion of the medical device, wherein geometric information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, and wherein the MRI system is unable to detect or will disregard MRI signals of the target markers within the anatomy as noise without using the stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system.

# Applicant's amended claim 8 limitations of

a medical device adapted to insert into an anatomy, the medical device having a plurality of target markers, wherein geometric information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy, and wherein MRI signals of the plurality of target markers within the anatomy are not detectable or disregardable as noise for MRI systems (a) without the MRI low-level signal detection process and (b) without using the stored geometric information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold.

## Applicant's amended claim 23 limitations of

storing geometric information for the plurality of target markers in a memory prior to insertion of the medical device into the anatomy; scanning a magnetic resonance image (MRI) of the anatomy; processing the scanned image by a MRI processor coupled to the memory; determining a location and orientation of the medical device inserted in the anatomy in relation to the anatomy based on the plurality of target markers; and displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of target markers within the anatomy are disregardable as noise or undetectable for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold.

# Applicant's amended claim 34 limitations of

storing geometric information for a plurality of target markers of a medical device in a memory prior to insertion of the medical device into an anatomy; scanning a magnetic resonance image (MRI) of the anatomy with the medical device inserted into the anatomy; processing the scanned image by a MRI processor coupled to the memory, the MRI processor having an MRI low-

level signal detection process; determining a location and orientation of the medical device in relation to the anatomy based on the geometric information of the plurality of target markers; and displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without using the stored geometric information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower an MRI signal detection threshold.

#### Applicant's amended claim 45 limitations of

storing geometric information for a plurality of target markers of a medical device in a memory prior to insertion of the medical device into an anatomy; scanning a magnetic resonance image (MRI) of the anatomy with the medical device inserted; processing the scanned image by a MRI processor coupled to the memory, the MRI processor having an MRI low-level signal detection process; determining a location and orientation of the medical device in relation to the anatomy based on detection of the plurality of target markers in relation to the medical device and each of the plurality of target markers, wherein geometric data of the medical device and the plurality of target markers is stored before the medical device is inserted into the anatomy; and displaying a precise image of the medical device within the anatomy, wherein MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without the MRI lowlevel signal detection process and without using the geometric information of the plurality of target markers to lower an MRI signal detection threshold,

#### nor Applicant's amended claim 47 limitations of

a medical device to insert into an anatomy, the medical device having a plurality of target markers, wherein geometric information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy, and wherein MRI signals of the plurality of target markers within the anatomy are undetectable or disregardable as noise for MRI systems without the MRI low-level signal detection process and without using the stored geometric information of the plurality of target markers to lower an MRI signal detection threshold, and wherein the geometric information includes geometric information of the medical device and each of the plurality of target markers to determine location and orientation of the medical device in relation to the anatomy.

Since neither Gillies, Badano, and therefore, nor the combination of the two, teach, disclose or suggest all the limitations of Applicant's amended claims 1, 8, 23, 34, 45 and 47, as listed above, Applicant's amended claims 1, 8, 23, 34, 45 and 47 are not obvious over Gillies in view of Badano since a *prima facie* case of obviousness has not been met under MPEP §2142. Additionally, the claims that directly or indirectly depend from amended claims 1, 8, 23, 34, 45 and 47, namely claims 4-7, 9-20 and 13-22, 24 and 27-33, 35 and 38-44, and 48-49, respectively, would also not be obvious over Gillies in view of Badano for the same reason.

Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejections for Claims 1, 4-10, 13-24, 27-35, 38-49 are respectfully requested.

B. It is asserted in the Office Action that Claims 2, 3, 11, 12, 25, 26, 36 and 37 are rejected in the Office Action under 35 U.S.C. § 103(a), as being unpatentable over Gillies in view of Badano, and further in view of U.S. Patent No. 5,817,017 issued to Young et al. ("Young"). Applicant respectfully traverses the aforementioned rejection for the following reasons.

Applicant's claims 2-3 either directly or indirectly depend from Amended claim 1.

Applicant's claims 11-12 either directly or indirectly depend from Amended claim 8.

Applicant's claims 25-26 either directly or indirectly depend from Amended claim 23.

Applicant's claims 36-37 either directly or indirectly depend from Amended claim 34. Applicant has addressed amended claims 1, 8, 23 and 34 regarding Gillies in view of Badano above in section I(A).

Young is relied on for disclosing a typical MRI system operating at 1.5 Tesla. Young, however, does not teach, disclose or suggest that markers on a medical device inserted in an anatomy are undetectable or discarded as noise in a basic MRI operating range unless an MRI low-level signal detection process is used based on previously stored information.

That is, even if Gillies, Badano and Young are combined in any way, the resulting invention would still not teach, disclose or suggest Applicant's amended claims 1, 8, 23 and 34 limitations, as listed above.

Since neither Gillies, Badano, Young, and therefore, nor the combination of the three, teach, disclose or suggest all the limitations of Applicant's amended claims 1, 8, 23 and 34, as listed above, Applicant's amended claims 1, 8, 23 and 34 are not obvious over Gillies in view of Badano and Young since a *prima facie* case of obviousness has not been met under MPEP §2142. Additionally, the claims that directly or indirectly depend from amended claims 1, 8, 23 and 34, namely claims 2-3, 11-12, 25-26, and 36-37, respectively, would also not be obvious over Gillies in view of Badano and Young for the same reason.

Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejections for Claims 2, 3, 11, 12, 25, 26, 36 and 37 are respectfully requested.

## CONCLUSION

In view of the foregoing, it is submitted that claims 1-49 patentably define the subject invention over the cited references of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes a telephone conference would be useful in moving the case forward, he is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly, extension of time fees.

Respectfully submitted,

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